PARTNERSHIP HEALTHPLAN OF CALIFORNIA

POLICY / PROCEDURE

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<tr><td colspan="4">Policy/Procedure Number: MPRP4001 (previously RP100401)</td><td colspan="3">Lead Department: Health Services</td></tr>
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☐ Internal Policy</td></tr>
<tr><td colspan="3">Original Date: 05/28/1999</td><td colspan="4">Next Review Date: 08/14/2025
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<tr><td colspan="4">Approval Signature: Robert Moore, MD, MPH, MBA</td><td colspan="3">Approval Date: 08/14/2024</td></tr>
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I. RELATED POLICIES:

A. MCUP3042 - Technology Assessment
B. MCRP4068 - Medical Benefit TAR Policy

II. IMPACTED DEPTS.:

A. Claims
B. Configuration

III. DEFINITIONS:

A. **Professional Organizations**: Nationally recognized healthcare professional organizations or academic healthcare organizations which promote evidence-based utilization of pharmaceuticals through publication of clinical practice guidelines. Organizations Partnership and the P & T Committee regularly rely on as resources for utilization management criteria include (but is not limited to): Infectious Disease Society of America (IDSA), American Medical Association (AMA), American Academy of Orthopedic Surgeons (AAOS), American Academy of Pediatrics (AAP), American Psychiatric Association (APA), American College of Rheumatology, American Academy of Dermatology (AAD), American Academy of Ophthalmology (AAO), American Association of Clinical Endocrinologists (AACE), American College of Cardiology (ACC).

B. **Compendia:** Resources widely accepted by the medical profession in the efficacious use of drugs. These resources include (but are not limited to): American Hospital Formulary Services (AHFS), Truven Health Analytics, Micromedex DrugDeX (DrugDex), Elsevier/Gold Standard Clinical Pharmacology, Wolters Kluwer Lexi-Drugs (Lexicomp®, Facts & Comparisons®, and UpToDate®), National Comprehensive Cancer Network (NCCN).

C. **Government bodies:** Partnership utilizes resources published by Federal or State entities that guide healthcare decisions and operational requirements for managed care Medi-Cal. Such organizations include (but are not limited to):
   1. CMS: The Centers for Medicare and Medicaid Services
   2. CDC: Centers for Disease Control and Prevention
   3. NIH: National Institutes of Health
   4. DHCS: Department of Health Care Services (California)

D. **PAD:** Physician Administered Drug. This is defined as a drug provided and administered to a member directly by a healthcare provider in a clinical setting other than in a pharmacy (including pharmacy infusion centers). This includes drugs that per package labeling *must* be administered by a healthcare provider (HCP) and drugs that are *typically* administered by HCPs (even if not specified in the package labeling). Medications given to a member to take at home for self-administration are *not* a PAD benefit, except for certain special programs such as family planning. PAD drugs are administered as part of the medical benefit.

E. **Partnership Medical Drug List (MDL):** The non-exhaustive list of medications coverable under PHC's medical drug benefit with or without authorization. The MDL is available only as a searchable electronic format and for provider use only.

F. **PAD Formulary:** This refers to the list(s) and databases Partnership uses to identify drugs that are payable as medical claims, with our without prior authorization and is not in reference to a distinct, single document available to those outside of Partnership to access. Partnership uses the MDL (see above) as the PAD formulary resource for external users to identify PAD coverage status &/or requirements.

G.

IV. ATTACHMENTS:

A. P&T Conflict of Interest Agreement

V. PURPOSE:

To describe the organization, operation, function and scope of the Partnership HealthPlan of California's (PHC's) Pharmacy and Therapeutics (P&T) Committee.

VI. POLICY / PROCEDURE:

A. The Pharmacy & Therapeutics (P&T) Committee as created under the authority of Partnership Chief Executive Officer (CEO) will make recommendations to the Physician Advisory Committee (PAC) regarding the content of the Medical Drug Benefit (Physician Administered Drugs/PAD), which includes new drug, and new billing code evaluations, new technology related to pharmaceuticals therapeutic class reviews, development of Prior Authorization Criteria, utilization management requirements, and other matters regarding the Partnership medical drug benefit.

B. The P&T Committee shall develop, review and update pharmaceutical coverage as follows:

1. Pharmaceutical Benefits
   a. All FDA-approved medications are a potential medical drug benefit when medical necessity is established, unless the medication is specifically prohibited from being reimbursed per the State Plan, State Plan Amendments, Title 22, DHCS All Plan Letters, or any State Policies or contracts which specify Partnership is not to reimburse, or is not responsible for reimbursement.
   b. Because all FDA-approved drugs are a potential benefit unless excluded from reimbursement as stated above, the P & T Committee shall consider whether or not a particular drug or pharmaceutical class shall be absent of prior authorization requirements based on therapeutic advantages in safety and efficacy, standards of care, and generally accepted place in therapy.
   c. The P&T Committee shall appropriately review the available CMS Healthcare Common Procedure Coding System (HCPCS) drug billing codes to make recommendations regarding revisions to adapt to both the number and types of drugs on the market.
   d. Partnership Pharmacy department and the P & T Committee will consider the medication represented by each CMS HCPCS code to be the benefit under review, and the HCPCS code is considered to be the billing methodology used to request reimbursement for the drug benefit. That is, it is the drug that is the benefit and not the HCPCS code *per se*.
   e. Because it is the drug that is considered to be the defined benefit rather than the HCPCS code assigned to the drug, the Partnership Pharmacy department may recommend the use of established CMS HCPCS codes to facilitate Partnership provider claims billing and reimbursement even when DHCS has not listed the established CMS HCPCS code as an accepted code when DHCS is the payer.
   f. Partnership Pharmacy department will research FDA-approved drugs with HCPCS codes which are unlisted/not covered by DHCS to ensure the drug itself is not excluded from reimbursement by the State Plan/Amendments, Title 22, All Plan Letters or other State policies that pertain to Managed Care Plans (MCP) and County Operated Health Systems

(COHS). When a drug is verified as being a potential benefit, regardless of the billing methodology, Partnership will make recommendations to the P & T Committee regarding coverage requirements for both the drug as benefit and the nationally accepted CMS HCPCS code assigned to the drug benefit.

g. The timing of the CMS announcements of new HCPCS codes being made effective for medical practice billing is such that the HCPCS codes cannot usually be reviewed by the P & T Committee ahead of the code effective dates. Thus the HCPCS codes will normally be presented to the P & T Committee for consent, with retroactive effective dates, with the understanding that the HCPCS code is the billing methodology for FDA-approved drugs and the drugs themselves are inherently already a potential benefit when not excluded as stated in sections above. The Committee shall consider the recommended utilization management for each drug/HCPCS code and may approve the recommendations retroactive to the effective date of the code via consent. Any Partnership voting member may make a motion to change the specifics of the presented utilization management, which will then be taken to vote.

h. The P&T Committee shall review and approve the medical drug benefit on an annual basis, with the totality of medical drug benefit review occurring over the course of the calendar year at quarterly P&T Committee meetings.

2. The quarterly P&T Committee meetings will review items proposed by the Plan and Committee members for utilization management of drugs/HCPS codes including:
   a. When multiple codes are available for a single drug entity, the Plan will recommend which Center for Medicare and Medicaid Services (CMS) valid code or codes the plan will accept for reimbursement purposes. Although this will generally mirror the codes accepted by DHCS for fee-for-service billing, it isn't a necessary requirement as managed care plans have the discretion to use active CMS billing codes as appropriate for the plan's own billing practices, as long as drug entity coverage meets DHCS and federal requirements.
   b. Utilization management as applied to provider billing of appropriate HCPCS codes may include (but is not limited to), requirements and limitations such as:
      1) Maximum daily doses based on either State Medi-Cal billing policy or U.S. Food and Drug Administration (FDA)-approved indications and dosing
      2) Maximum treatment duration or frequency of service dates (interval between doses) based on either State Medi-Cal billing policy, FDA-approved indications or compendia, professional organizations, or government bodies
      3) Age limits based on either State Medi-Cal billing policy or FDA-approved indications
      4) Scope of practice requirements – that is, prescriber specialty or credentials when standard of care is such that an appropriate specialist oversee the pharmaceutical treatment and disease state management for the purpose of member safety
      5) Service location type (e.g. dialysis center, medical office, infusion center, outpatient hospital/surgery center, etc)
      6) Prior Authorization requirements – these may mirror State Medi-Cal billing policies or the Plan may establish such requirements and criteria distinct from Medi-Cal fee-for-service billing policies. When distinct from Medi-Cal billing policies, the Plan will use the following to recommend to the Committee both when a TAR will be required and what the criteria for use shall be:
         a) Place in therapy per FDA indication or through consultation of medical compendia or professional organization published treatment guidelines
         b) Necessary safety screening and monitoring
         c) Efficacy limitations
         d) Step therapy or therapeutic interchange protocols for the purpose of financial management shall be utilized only when comparable therapeutic alternatives, which are similar in safety and efficacy, are available for providers to utilize.

e) The P & T Committee shall consider the therapeutic advantages in relation to the interaction of a drug therapy regimen and the use of other health care services, including non-pharmacologic treatments.

3. The P&T Committee shall perform an initial review of drugs that are clinically effective. If two (2) or more drugs have the same therapeutic advantages in regard to safety and efficacy, the P&T Committee may consider total health care costs to achieve appropriate, safe, and cost effective drug therapy.
4. The P&T Committee shall review and update Plan policies that guide the medical drug benefit, Exceptions (prior authorizations), P & T, Pharmacy Programs and other utilization management processes including:
   a. Drug utilization review
   b. MCRP4068 - Medical Benefit Medication TAR Policy
   c. MCRP4064 - Continuation of Prescription Drugs
   d. MPRP4001 - Pharmacy and Therapeutics (P & T) Committee
   e. MPRP4034 - Pharmaceutical Patient Safety
   f. MCRP4066 - AB1114 Benefit Implementation and Oversight
   g. MCRP4065 - Drug Utilization Review (DUR) Program
5. The P&T Committee shall evaluate and analyze treatment protocols and procedures (policies and clinical guidelines) related to the medical drug benefit at least annually, and consistent with CMS policy guidelines and instructions.

C. Technology Review: The CMO or physician designee may request input from an appropriate specialist within the community prior to presenting the request to the P&T Committee, Quality/Utilization Advisory Committee (Q/UAC), and/or PAC. This specialist must have expertise in the technology under review. The decision to consult a specialist will depend on the nature of the technology being considered, and will be made on a case-by-case basis. (Technology Assessment Policy MCUP3042).

D. Partnership shall remain accountable to CMS and DHCS for the integrity, expertise, and qualifications of the P&T Committee.

E. Partnership shall ensure that the P&T Committee uses appropriate scientific and economic criteria when considering utilization management activities that affect access to drugs and drug classes such as:
   1. Access to FDA-approved drugs not otherwise excluded by DHCS, CMS, or California State or Federal requirements. The process for submitting TARs for drugs that require prior authorization for medical necessity is per policy MCRP4068.
   2. PAD billing requirements, restrictions and limits (see VI.B.2.b.)
   3. Therapeutic interchange and Step therapy protocols: Defined through the application of Prior Authorization criteria when prerequisite or alternative therapy is required.

F. The P&T Committee shall adhere to P&T guidelines that CMS and DHCS shall, from time to time, promulgate with regard to subject areas, including:
   1. Membership;
   2. Conflict of interest;
   3. Meeting schedule;
   4. Meeting minutes;
   5. Therapeutic classes;
   6. Drug review and inclusion;
   7. Utilization management and review;
   8. Educational programs for Providers:
      a. For Prescribers: A Partnership clinical pharmacist and/or Partnership Medical Director meets annually with selected provider sites during “academic detailing visits” at which time, any issues regarding continuity and coordination of pharmaceutical care from prescribers are addressed.

G. Partnership shall adopt all P&T Committee recommendations regarding the utilization management of medical

drugs when subsequently approved by the PAC unless otherwise dictated by State requirements or system limitations discovered subsequent to P & T Committee approval. In the latter, all committees will be notified of reversal or modification of the recommendation to meet regulatory or system requirements/limitations as soon as possible.

H. Partnership shall consider recommendations from the P&T Committee in the following areas as advisory and not binding:
   1. Review of policies that guide utilization management; and
   2. Evaluation and analysis of treatment protocols and procedures.

I. The P&T Committee shall maintain written documentation of decisions regarding medical drug benefit development and revision and utilization management activities.

J. GOALS: To assure continuing member access to a quality driven, cost-effective, rational drug benefit through the Partnership Formulary and prescription drug preauthorization process.

K. Organization and Operation
   1. Membership
      a. The committee shall be comprised of the following members
         1) Partnership Chief Medical Officer (CMO)
         2) Partnership Director of Pharmacy, who shall serve as secretary or as acting chair when designated as such by the CMO
         3) Partnership Clinical Pharmacist
         4) Partnership Medical Director
         5) Practicing physician(s) representing primary care specialties including, but not limited to, Family Practice, Internal Medicine, and Pediatrics
         6) Practicing physician representing Psychiatry
         7) Practicing community pharmacist(s)
         8) Other representatives as determined appropriate by the Committee.
      b. Membership of the P&T Committee shall include a majority of members who are practicing physicians or practicing pharmacists with:
         1) At least one (1) practicing physician and at least one (1) practicing pharmacist who do not have a conflict of interest with respect to Partnership and pharmaceutical manufacturers;
         2) At least one (I) practicing physician and at least one (1) practicing pharmacist who are independent experts in the care of the elderly or disabled persons; and
         3) Representation from various clinical specialties.
      c. The Partnership Chief Medical Officer or Partnership Director of Pharmacy as delegated by the CMO shall serve as the Committee Chairman
      d. Non-voting members.
         1) Partnership Chief Health Services Officer
         2) Partnership Senior Director of Provider Relations (ad hoc)
         3) Partnership Quality Improvement representative (ad hoc)
         4) Other invited experts such as, consultant pharmacists or consultant physicians, etc.

      e. The distribution of physician and pharmacist membership should represent the Partnership member population.
   2. A quorum defined by 1/3 of the practicing members must be present in order to conduct the P&T Committee meeting. A consensus recommendation is made on drug coverage changes and drug/benefit policies. If no consensus is established, the issue is voted on with the decision determined by majority vote of the voting membership.
   3. Voting membership includes practicing members from the community, Partnership CMO, Partnership medical directors, Partnership Director of Pharmacy, and Partnership Clinical Pharmacists.
   4. The P&T Committee meets at least four times per year. If urgent matters pertaining to the selection or utilization of drugs arise between meetings, a telephone meeting may be conducted with the members, or a poll of members by fax or email may be utilized. (See section VI.L.2.)
   5. An agenda and supplementary materials, including minutes of the previous meeting, are prepared

and submitted to the committee members in sufficient time before the meeting to ensure proper review of the material. This is the responsibility of the secretary.

6. Minutes of the committee proceedings are prepared and signed and maintained in the permanent records of Partnership.
7. All recommendations by the committee for additions, or changes to the medical drug benefit are forwarded to the PAC for approval. Any additions, deletions or changes to the medical drug benefit or to prior authorization criteria will take effect *no sooner* than the first day of the month after the PAC meeting, and *no later* than the 2nd week of the quarter following P&T and PAC, unless the recommended change is retroactive and presented for consent (see VI.B.e) Specific effective dates for changes will be established at each P & T meeting. This is to allow time to configure changes in Partnership's claim systems, notify physicians, pharmacists and other providers, and to change internal systems/processes if needed.
8. Maintenance of Partnership medical drug benefit information and distribution of Partnership Medical Drug List: providers and members are notified multiple times per calendar year on how to access medical drug benefit information which is maintained online on the Plan's website.
   a. Providers are notified in the quarterly Provider Newsletter distributed by the CMO.
      1) The language shall direct medical providers to the Partnership website locations where information may be found regarding:
         a) Changes to the medical drug benefit (P & T Updates)
            i. Revised billing requirements, limitations, or restrictions
            ii. New and Revised drug TAR requirements
         b) Partnership and State Medi-Cal Covered Drug Lists
         c) Utilization management criteria and policies
         d) Pre-authorization (aka Prior Authorization or TAR) submission information
   b. In addition, providers are notified by the Partnership Claims department when a TAR requirement is added to a code or drug that previously did not require prior authorization and have utilization of the drug within past 120 days, through the issuance of an IPN (Important Provider Announcement), 60 days prior to implementation of the change. IPNs are posted on the Provider Claims pages of the Partnership website.
   c. Members are notified in the written semi-annual newsletter by mail (distributed by Partnership Member Services):
      1) Newsletter notification language is reviewed at least annually by the P & T Committee
      2) The language shall direct the member to the Partnership website locations where information may be found regarding:
         a) Changes to the medical drug benefit (P & T Updates)
            i. Revised billing requirements, limitations, or restrictions
            ii. New and Revised drug TAR requirements
         b) Partnership and State Medi-Cal Covered Drug Lists
         c) Pre-authorization (aka Prior Authorization or TAR) submission information
   d. The Partnership pharmacy department shall maintain the P&T Updates page on the Partnership Website, updated quarterly prior to the effective date.
      1) The P & T Updates document will be posted online no later than two (2) weeks following PAC approval. In the case of interim plan coverage determinations, the retroactive effective date will be included in the P & T updates document.
      2) At least one previous calendar year's updates will remain available, together with the current calendar year.
   e. The Plan's Policies and Procedures are available to practitioners on the Plan's website, which includes Policies, Clinical Treatment Guidelines, and the Provider Manual for medical providers.
   f. Any of the above are available upon request to medical providers who do not have online or FAX access. A provider may contact the Pharmacy Department to have the most recent updates sent by mail:

Partnership HealthPlan of California, Pharmacy Services Department
4665 Business Center Drive
Fairfield, CA 94534
(707) 863-4414

g. Online medical drug coverage resources will be updated when benefit changes are made:
   1) Effective Date: The effective date established by the P&T Committee, or by the plan in the event of changes that occur outside of P&T (see VI.L.2, below). This is the date that the approved change will be applied to claims for service dates on or after the specified date.
   2) The Partnership's medical drug benefit search tool, PHC MDL Navigator™, was implemented in July 2022.
      a) The Partnership Pharmacy department maintains the PHC MDL Navigator™ online search tool to provide medical providers and Partnership staff with the billing requirements for PADs.
   3) Standard updates to the medical drug benefit search tool (not retroactive) are timed such that the search tool information should mirror current requirements in Partnership claim reimbursement systems. Benefit changes following P & T are published in the search tool no later than the evening before the effective date.
   4) Note that when following DHCS State Medi-Cal billing policy announcements, notifications are typically retroactive and thus the search tool cannot always be proactive – the Plan acts as soon as possible upon receipt of notification and notifies the P & T Committee of retroactive State benefit changes.

L. Functions: The functions and scope of this committee are designed to promote quality in the use of PADs, to manage and control drug costs, and to continue to support the development of prior authorization criteria treatment guidelines based on clinical efficacy and sound pharmaco-economic principles.
Formularies:
1. Maintain a PAD covered code/drug lists, acceptable for use in outpatient medical care settings, which is reviewed and updated on a quarterly basis based on a standing class review schedule. Each drug class is reviewed at least annually (no more than 1 year and 2 weeks from previous review).
2. The PAD formulary (covered code/drug lists) functions as a closed formulary – meaning new drugs and new formulations of existing drugs are by default not on the formulary until such time as they are added to the formulary by the P & T Committee. Non-formulary drugs require prior authorization except when a provider contract overrides this requirement, such as emergency department claims.
3. Interim code/drug coverage updates including prior authorization criteria may be made by Partnership Pharmacy department such as those immediately necessary due to market changes brought about by:
   a. New CMS HCPCS drug billing codes with an effective date earlier than the next P & T review & PAC implementation dates
   b. Market shortages of formulary preferred PADs
   c. All interim updates will be reviewed for consent (unless change is proposed by a committee member) by the P&T Committee at next scheduled meeting.
   d. Drugs requiring implementation of interim prior authorization criteria will be sent to the committee for comment and vote by email. The result will then be included in the next PAC meeting for approval and implemented at the first of the month following the PAC meeting. Such items will be included as addendum to the minutes in the next occurring P&T packet, not an item for further P&T action or consent.
4. Review and make available as a benefit based on medical necessity of any new FDA-approved drugs not yet assigned to a specific HCPCS code by CMS and billable by National Drug Code together with a code intended for non-classified drugs (a NOC, not otherwise classified code), such as J3490 (unclassified drugs) or J3590 (unclassified biologics).

a. The P & T Committee will review new and existing unclassified drugs for inclusion in (or exclusion from) the list of drugs coverable without a TAR when billed under a NOC code. The plan shall be responsible for ensuring that as drugs are assigned specific billing codes by CMS, they shall be removed from the NOC covered drug list.
b. Note that drug coverage itself does not change when a billing code is added or changed, only the billing methodology. Providers are informed of billing code changes through DHCS Provider Bulletins, Partnership P & T Updates, and CMS HCPCS announcements. See VI.K.8 for notification details.

5. Establish new TAR requirement for a drug previously covered without a TAR. Such a change will occur when either:
   a. Interim change: DHCS/State Medi-Cal adds a TAR requirement and the Plan agrees with the TAR requirement due to new information regarding safety, efficacy, place in therapy, or based on pharmacoeconomic principles when other factors are equal.
      1) It is recognized that the State may apply a TAR requirement or remove a drug from its covered code list due to manufacturer contracts (rebates) resulting in changes in preferred drug status, and such considerations are not required to be followed by the health plan.

   or

      2) The P & T Committee approves the change as recommended by health plan independently of any State fee-for-service billing policy that may exist.

      See VI.K.8 for notification process/resources for new TAR requirements.

      Note that only changes in *drug* coverage status (changes to utilization management or TAR criteria) are put forth as P & T and PAC approval items. Operational changes that affect billing requirements not related to utilization management, such as a drug being assigned a new HCPCS code, shall be implemented internally by the Plan. For example: a drug that required a TAR under its prior billing code (or unclassified status) and continues to require a TAR with the new billing code, is not considered to be subject to P & T and PAC approval because no change in the drug's accessibility has occurred.

6. The P&T Committee shall base clinical decisions regarding utilization management on the strength of scientific evidence, standards of practice, and safety and efficacy considerations. The P&T Committee will use criteria for utilization management decisions which takes into account the following:
   a. Pharmaceutical class – i.e., taking into account which drug classes are available as a Partnership benefit vs those that are either excluded or carved out to State fee-for-service Medi-Cal.
   b. Classes preferred or covered at any level
   c. Lists of preferred drugs
   d. Considerations for limiting or excluding drugs in certain classes in alignment with professional organization guidelines and Medi-Cal Rx policy, (see State Medi-Cal, MCP Scope Document v.6). For example:
      1) Antibiotic stewardship and standards of care
      2) Evidence-based utilization of chemotherapeutic agents (e.g., NCCN evidence-based recommendations)
      3) Drugs dispensed by a pharmacy directly to the member and billable to Medi-Cal Rx
      4) Any drug regardless of class when prescribed for pharmacy fulfillment for the purpose of taking/giving the medication at home or administered by a pharmacist (e.g., vaccines) or by an infusion pharmacy (aka Outpatient Prescription Drugs)
      5) Diabetic supplies (insulin syringes, pen needles, lancets, test strips) when supplied by a pharmacy
      6) Metered dose inhaler spacers (inhaler assistive devices) and peak flow meters when supplied by a pharmacy
      7) Emergency Use Authorization (EUA) drug therapies
      8) Drugs specified by DHCS as being non-capitated for managed care (i.e., carved-out to State Medi-Cal fee-for-service): HIV/AIDS, Hemophilia, Alcohol and Opiate detoxification/maintenance,

Antipsychotics & limited antidepressants.

e. Therapeutic interchange, step therapy or other utilization management methods described in section VI.E.3

f. Within each class of pharmaceuticals, the committee will consider:
   1) those agents preferred or covered at any level
   2) the criteria for prior authorization of any pharmaceutical
   3) exceptions processes available to members
   4) substitutions that will be allowed automatically or with permission from the prescribing practitioner
   5) evidence that preferred status agents can produce similar or better results for a majority of the population than other pharmaceuticals in the same class;
   6) other requirements, restrictions, limitations or incentives that apply to the use of certain pharmaceuticals as described in section V1. B.2.B.

7. The P&T Committee considerations of proposed new coverage and coverage changes (including prior authorization criteria) of all FDA-approved drugs shall be based on clinical evidence which includes the following: Relevant findings of government agencies
   a. Medical associations
   b. National commissions
   c. Peer-reviewed journals
   d. Authoritative compendia
   e. Confirmation that the drug has an approved indication by the FDA
   f. Input from selected relevant specialists or professionals, if not represented on the P&T Committee, who have expertise in the drug being reviewed
   g. Randomized clinical trials
   h. Pharmacoeconomic studies
   i. Outcomes research data
   j. Other information as it determines appropriate.

8. The P&T Committee shall make reasonable effort to review a new chemical entity or new FDA clinical indicator within ninety (90) calendar days after release into the market, and shall make a decision within one hundred eighty (180) calendar days after release into the market.
   a. If the P&T Committee fails to meet timeframes of this policy, Partnership shall provide a clinical justification for such delay to DHCS upon request

9. The following types of products are not a benefit for Partnership Medi-Cal members and are not subject to review by the P&T Committee and as such are not available by a Treatment Authorization Request, regardless of whether Partnership is the secondary or primary payer:
   a) SSA 1927(k), "Covered Outpatient Drugs": This section of the Social Security Act serves to define what is (and isn't) an outpatient drug benefit for Medicaid beneficiaries. "Covered Outpatient Drugs" do not include any drug, biological product or insulin, provided as part of, or as incident to, the provision of and billing for medical or institutional services. Outpatient drugs that are *not* incident to a medical or institutional service, such as those provided by a pharmacy, fall under the scope of the pharmacy benefit (Medi-Cal Rx).
   b) Drugs not approved by the FDA for the treatment or diagnosis of any medical condition. This does not preclude those drugs with an approved FDA indication used with "off label" indications.
   c) Products not evaluated by the FDA for safety, purity & efficacy. This includes herbal products, dietary/food supplements, medical foods and non-prescription treatments or products, and DESI 5 and 6 drugs.
      a. Non-FDA approved and OTC product exceptions for PADs (may be covered):
         i. When the unapproved or OTC drug is covered by State Medi-Cal
         ii. Not covered by Medi-Cal but approved by P & T Committee and PAC as an enhanced Partnership benefit when a drug product has an accepted place in therapy.

d) Any Products/Drugs when intended to be used for the treatment of erectile dysfunction, infertility or other sexual dysfunction.
e) Drugs/Products used for cosmetic purposes in the absence of medical necessity
f) Common household items
g) Medical Cannabis
h) Drugs used for the purpose of enhancing athletic (including weight or muscle gain) or mental performance in the absence of medical necessity
i) Drugs purchased in another country
j) FDA Schedule 1 controlled substances
k) Over-the-Counter (OTC) drinks/shakes/bars for assistance with weight loss
l) Enteral nutrition products used orally as a convenient alternative to preparing and/or consuming regular solid or pureed foods
m) Infant formulas that are available through the Women, Infants, and Children (WIC) program
n) Individual drugs or HCPCS drug codes as instructed through DHCS All Plan Letters or State Amendments or California Code of Regulations Title 22 as being a non-reimbursable and the plan has not placed the drug on the medical drug benefit as a benefit enhancement over that which DHCS provides to Stated Fee-For-Service. Coverage for California Children Services (CCS) and Early and Periodic Screening, Diagnostic and Treatment (EPSDT) beneficiaries may be exempt from non-reimbursable designation, depending on the instruction from state agencies for specific drugs and non-drug products.
o) Medications provided to a member to self-administer at home (or to be administered by a caregiver) are not a medical benefit except when included under a specific benefit plan such as that defined under the Family Planning Benefit. Unless otherwise allowed per provider contract, medical providers can submit TARs and claims directly to Partnership only for those services *rendered in the medical setting for a specific date of service.* Providing additional medication supply for a member to take on their own outside of the medical office/clinic/hospital falls within the scope of the pharmacy benefit, administered by Medi-Cal Rx/Prime Therapeutics and is not covered by Partnership.

10. Partnership shall require all P&T Committee members to sign a conflict of interest statement that:
    a. Reveals economic or other relationships with entities that may influence pharmaceutical decisions; and
        1) Disclose such conflicts to other committee members.
    b. A committee member shall excuse himself or herself from any discussions or votes associated with a conflict of interest issue.
11. P&T Committee recommends, initiates, or directs drug utilization review (DUR) and quality assurance programs. This includes recommending target drugs, drug classes or disease states to review, approving use criteria before review, reviewing results when completed, and making recommendations to appropriate providers or other Partnership committees.
12. Oversight: P&T Committee is responsible to ensure that contracted emergency departments can provide drugs to members under emergency circumstances in sufficient quantities to last until the member can reasonably be expected to have a prescription filled. On a biannual basis, the Committee reviews documentation from Partnership contracted emergency departments that they have a policy on dispensing drugs under emergency circumstances.

VII. REFERENCES:

A. California Department of Health Care Services (DHCS) Medicaid State Plan, Title 19 https://www.dhcs.ca.gov/formsandpubs/laws/pages/californistateplan.aspx
B. California Code of Regulation, Title 22 https://govt.westlaw.com/calregs/Index?transitionType=Default&contextData=%28sc.Default%29
C. State Medi-Cal Provider Manual Part 1: MCP: County Organized Health System (COHS) (updated August 2020) https://files.medi-cal.ca.gov/pubsdoco/Publications/masters-MTP/Part1/mcpcohs.pdf
D. DHCS Medi-Cal Rx Scope Document V.6 https://www.dhcs.ca.gov/provgovpart/pharmacy/Documents/MediCal-Rx-Scope-V06-2-8-2022.pdf

E. **DHCS Provider Manual, General – Part 1: MCP: County Organized Health System (COHS) (mcp cohs)** **https://mcweb.apps.prd.cammis.medi-cal.ca.gov/assets/9BF41B56-5B24-4965-96E6-9F2892DB5AC1/mcpcohs.pdf?access_token=6UyVkRRfByXTZEWIh8j8QaYylPyP5ULO**

VIII. DISTRIBUTION:

A. Partnership Department Directors
B. Partnership Provider Manual

IX. POSITION RESPONSIBLE FOR IMPLEMENTING PROCEDURE:

Pharmacy Services Director

X. REVISION DATES:

Medi-Cal

07/06/00; 10/04/01; 04/18/02; 10/3/02; 01/15/04; 04/07/05; 01/18/07; 01/15/09; 09/7/10; 10/28/10; 08/02/12; 08/29/13; 10/01/15; 10/06/16; 04/06/17; 08/09/17; *06/13/18; 05/08/19; 11/13/19; 11/11/20; 11/10/21; 08/10/22, 08/09/23, 08/14/2024

*Through 2017, Approval Date reflective of the Pharmacy & Therapeutics Committee meeting date. Effective January 2018, Approval Date reflects that of the Physician Advisory Committee's meeting date.

PREVIOUSLY APPLIED TO:

PartnershipAdvantage:
MPRP4001 - 01/18/2007 – 01/01/2015

Healthy Families:
MPRP4001 - 10/28/10 to 03/01/2013

Healthy Kids
01/18/2007; 01/15/09; 09/7/10; 10/28/10; 08/02/12; 08/29/13; 10/1/15; 10/06/16 to 12/01/16 (Healthy Kids program ended 12/01/2016)

XI. POLICY DISCLAIMER:

A. In accordance with the California Health and Safety Code, Section 1363.5, this policy was developed with involvement from actively practicing health care providers and meets these provisions:
   1. Consistent with sound clinical principles and processes;
   2. Evaluated and updated at least annually;
   3. If used as the basis of a decision to modify, delay or deny services in a specific case, the criteria will be disclosed to the provider and/or enrollee upon request.
B. The materials provided are guidelines used by Partnership to authorize, modify or deny services for persons with similar illnesses or conditions. Specific care and treatment may vary depending on individual need and the benefits covered under Partnership.
C. Partnership's authorization requirements comply with the requirements for parity in mental health and substance use disorder benefits in 42 CFR 438.910.